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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/403,092 10/15/99 HOFMANN J 038311/0103

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EXAMINER

ZEMAN, R

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

10/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/403,092

Applicant(s)
Hofmann et al.

Examiner
Robert A. Zeman

Group Art Unit
1645



☒ Responsive to communication(s) filed on Oct 15, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 17-34 is/are pending in the application.

Of the above, claim(s) 27 and 28 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 17-26 and 29-34 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 17-34 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

Applicant's election of Group I, **without** traverse, in Paper No. 9 is acknowledged.

Claims 27 and 28 have been withdrawn from consideration. Claims 17-26 and 29-34 are pending and currently under examination.

Specification

M - no generic

The use of the various trademarks has been noted throughout this application (see pages 2, 3, 8, and 9 for examples). Trademarks should be capitalized wherever they appear and be accompanied by the corresponding generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

maintain

Claims 24-25, 27 and 30 are objected to because of the following informalities:

Dictyocaulus viviparus is misspelled. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated protein comprising the amino acid sequence of SEQ ID NO:30, does not reasonably provide enablement for “a part thereof” of the aforementioned isolated protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The specification provides no guidance for making said protein in accordance with the claimed invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid which comprises SEQ ID NO:29, does not reasonably provide enablement for “a part thereof” of the aforementioned isolated nucleic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The specification provides no guidance for making said nucleic acid in accordance with the claimed invention.

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Claims 24-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for oligonucleotides which comprises SEQ ID NO:8; SEQ ID NO:9; SEQ ID NO:10; SEQ ID NO:10; SEQ ID NO:11; SEQ ID NO:12; SEQ ID NO:13; or SEQ ID NO:14, does not reasonably provide enablement for “a part thereof” of the aforementioned oligonucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The specification provides no guidance for making said oligonucleotides in accordance with the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 and 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is rendered vague and indefinite by the use of the term “parts thereof”. The specification is deficient in defining what is meant by a “a part thereof”. Applicant fails to disclose what percentage of the total sequence must be present in order for a polypeptide to be considered a “part” of said protein or what biochemical/immunological properties must be present in order for a polypeptide to be considered a “part thereof”. Would a single amino acid be

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considered a “part thereof”? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 23 is rendered vague and indefinite by the use of the term “parts thereof”. The specification is deficient in defining what is meant by a “a part thereof”. The specification is deficient in defining what is meant by a “a part thereof”. Applicant fails to disclose what percentage of the total sequence must be present in order for a polynucleotide to be considered “a part thereof” of said isolated nucleic acid or what biochemical/hybridizational properties must be present in order for a polynucleotide to be considered a “a part thereof”. Would a single nucleotide be considered a “part thereof”? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 24-25 are rendered vague and indefinite by the use of the term “parts thereof”. The specification is deficient in defining what is meant by a “a part thereof”. The specification is deficient in defining what is meant by a “a part thereof”. Applicant fails to disclose what percentage of the total sequence must be present in order for a polynucleotide to be considered “a part thereof” of said oligonucleotides or what biochemical/hybridizational properties must be present in order for a polynucleotide to be considered a “a part thereof”. Would a single nucleotide be considered a “part thereof”? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 26 is rendered vague and indefinite by use of the phrase “expressing the cDNA clone obtained according to claim 24”. Since it is impossible to know what “clones” would be

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obtained according to claim 24, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The instant claims are drawn to an immunogenic protein from *Dictyocaulus viviparus* with a molecular weight of approximately 16,000 \pm 1500 daltons and an isoelectric point of approximately 5.6. The aforementioned claims are also drawn to an isolated nucleic acid encoding said protein, methods for identifying said nucleic acid and methods for producing the recombinant form of the claimed protein using said nucleic acid (as well as the vector and host

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cells required for said recombinant protein expression). Finally, the claims are drawn to a vaccine comprising said protein and a method of using said vaccine for immunizing cattle, kits comprising either the aforementioned protein or the aforementioned nucleic acid.

Claims 17-20, 29-31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over de Leeuw et al. (Veterinary Parasitology Vol. 39 No. 1-2, 1991, pages 137-147, IDS-10).

de Leeuw et al. disclose an immunogenic protein isolated from *Dictyocaulus viviparus* with a molecular weight of 17,000 daltons. Even though the disclosed immunogenic protein is not further characterized in terms of its amino acid sequences or its isoelectric point, de Leeuw anticipates these limitations since said limitations reasonably appear to be the identification of new features of a protein already known in the art. While de Leeuw et al. disclose the use of said immunogenic protein in diagnostic methods they do not explicitly disclose the bundling of the disclosed protein in a kit. However, it would have been obvious for one of skill in the art to bundle said protein in a diagnostic kit in order to reduce costs. It would have been equally obvious for one of skill in the art to combine the disclosed protein with a suitable adjuvant or carrier for use in a vaccine since such a combination is standard practice within the art and since nothing in such combination distinguishes it over the protein of de Leeuw et al.

Claims 17-26 and 31-34 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Britton et al. (Molecular and Biochemical Parasitology, Vol. 72 No. 1-2, 1995, pages 77-88, IDS-10).

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Britton et al. disclose an immunogenic protein isolated from *Dictyocaulus viviparus* with a molecular weight of 14,000-15,000 daltons. Even though the disclosed immunogenic protein is not further characterized in terms of its amino acid sequences or its isoelectric point, Britton et al. anticipates these limitations since said limitations reasonably appear to be the identification of new features of a protein already known in the art. Britton et al. also disclose a cDNA sequence for said immunogenic protein, methods for determining said cDNA sequence, and methods for the utilization of recombinant vectors and host cells. While Britton et al. do not disclose the sequence of SEQ ID NO:29 *per se*, the sequences disclosed fall within the limitations of the claims. While Britton et al. disclose the use of the nucleic acid encoding said immunogenic protein in diagnostic methods they do not explicitly disclose the bundling of the disclosed protein in a kit. However, it would have been obvious for one of skill in the art to bundle said nucleic acid in a diagnostic kit in order to reduce costs.

Claims 17-26 and 29-34 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schnieder (International Journal of Parasitology, Vol. 22 No. 7, 1992, pages 933-938, IDS-10).

Schnieder discloses an immunogenic protein isolated from *Dictyocaulus viviparus* with a molecular weight of approximately 18,000 daltons. Even though the disclosed immunogenic protein is not further characterized in terms of its amino acid sequences or its isoelectric point, Schnieder anticipates these limitations since said limitations reasonably appear to be the identification of new features of a protein already known in the art. While Schnieder discloses

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the use of said immunogenic protein in diagnostic methods he doesn't explicitly disclose the bundling of the disclosed protein in a kit. However, it would have been obvious for one of skill in the art to bundle said protein in a diagnostic kit in order to reduce costs. It would have been equally obvious for one of skill in the art to combine the disclosed protein with a suitable adjuvant or carrier for use in a vaccine since such a combination is standard practice within the art and nothing in the combination distinguishes over Schnieder. Schnieder also discloses methods for determining the nucleotide sequence for said immunogenic protein by generating a cDNA sequence library. Schnieder also discloses methods for the utilization of recombinant vectors and host cells for the expression of recombinant proteins. While Schnieder doesn't disclose the sequence of SEQ ID NO:29 *per se*, the sequences disclosed fall within the limitations of the claims. Finally, even though Schnieder discloses the use of the nucleic acid encoding said immunogenic protein in diagnostic methods he does not explicitly disclose the bundling of the disclosed protein in a kit. However, it would have been obvious for one of skill in the art to bundle said nucleic acid in a diagnostic kit in order to reduce costs.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.


DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

October 30, 2000